

## PATENT COOPERATION TREATY

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PCT.3912.DES	<b>FOR FURTHER ACTION</b> See Form PCT/IPEA/416	
International application No. PCT/ZA2004/000074	International filing date (day/month/year) 02.07.2004	Priority date (day/month/year) 02.07.2003
International Patent Classification (IPC) or national classification and IPC A61K9/00, A61K9/70		
Applicant TUNGUY-DESMARAIS, Peter.		
<p>1. This report is the International preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand  29.04.2005	Date of completion of this report  14.10.2005	
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Rodriguez-Palmero, M  Telephone No. +49 89 2399-7871	



**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/ZA2004/000074

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-4 as originally filed

**Claims, Numbers**

1-7 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
- ☐ the entire international application,
  - ☒ claims Nos. 1 with respect to industrial applicability  
because:
    - ☒ the said international application, or the said claims Nos. 1 with respect to industrial applicability relate to the following subject matter which does not require an international preliminary examination (specify):  
**see separate sheet**
    - ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
    - ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
    - ☐ no international search report has been established for the said claims Nos.
    - ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
      - the written form ☐ has not been furnished
      - ☐ does not comply with the standard
      - the computer readable form ☐ has not been furnished
      - ☐ does not comply with the standard
    - ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
    - ☐ See separate sheet for further details

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	1,6,7
	No: Claims	2-5
Inventive step (IS)	Yes: Claims	1,6,7
	No: Claims	2-5
Industrial applicability (IA)	Yes: Claims	2-7
	No: Claims	-

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

Claim 1 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim (Article 34(4)(a)(I) PCT).

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. The following documents are referred to in this communication:

- D1: EP-A-0 576 748 (AKYUZ RALPH ; MERAT PIERRE H (US)) 5 January 1994.
- D2: GB 965 236 A (BEIERSDORF & CO A G P) 29 July 1964.
- D3: WO 98/29085 A (BETTLE GRISCOM ; COURY WILLIAM S (US); AMERICAN MEDICAL RES LLC (US);) 9 July 1998.
- D4: ALTMAN P M: "AUSTRALIAN TEA TREE OIL-A NATURAL ANTISEPTIC" AUSTRALIAN JOURNAL OF BIOTECHNOLOGY, vol. 3, no. 4, October 1989, pages 247-248.

1.1 Unless indicated, reference is made to the passages indicated in the international search report.

**2. Novelty (Art. 33(2) PCT)**

2.1 Present claims 2-7 concern the first medical use of a composition comprising a water repellent agent and an antimicrobial agent in a film forming liquid capable of being instilled in the outer ear canal in droplet form.

2.2 D1 discloses a composition in the form of lotion or mousse containing a wax and suitable wetting and emulsifying agents, a moisture barrier agent and suitable antiseptics, astringents, antibacterial agents and emollients to form a thin protective

coating (i.e. a film) over the treated area which will provide protection against a wide range of hostile or hazardous substances. The composition mentioned in claim 6 is a lotion comprising dimethylpolysiloxane as a film former and water proofing compound (h) and benzalkonium chloride as an antibacterial agent (l). Such a lotion is considered to be capable of being instilled in the outer ear canal in droplet form and it is therefore considered to fall within the scope of present claims 2-5.

D2 concerns compositions for application to the feet. On application to the skin, the composition produces a cohesive, thin film on the surface of the skin, which is largely resistant to water aqueous secretions. It comprises polysiloxane, an antibacterial substance and a volatile liquid. The compositions may be in form of liquid emulsion. They contain a major proportion of an easily vaporisable ingredient such as isopropanol, ethanol or water. None of these components is considered to be unsuitable for being in a composition for instillation in the outer ear canal. In fact, many compositions used for treating the so called swimmer's ear comprise alcohol because as it evaporates, it absorbs the water, helps dry out the ear and may even kill the bacteria and fungi that cause the infection.

D3 relates to film-forming compositions that, when applied to the skin, form a hydrophobic film that covers the skin as the liquid carrier evaporates. The film excludes water and water-soluble cleansing agents from the surface of the skin. Antiviral and antibacterial agents can be incorporated therein. The compositions disclosed therein can be in form of a lotion and the liquid carrier can be water or a lower molecular weight alcohol. They are therefore considered to be suitable for being instilled in the outer ear canal.

2.3 Therefore, the subject-matter of present claims 2-5 cannot be considered novel in the light of D1-D3. It should be mentioned that claims 2-5 concern compositions **suitable** for being instilled in the outer ear canal. The fact that the prior art documents do not mention this application does not imply that the compositions are not suitable for it.

2.4 None of the documents cited in the international search report anticipates the subject-matter of claims 1, 6 and 7. Therefore, said claims are considered novel.

**3. Inventive Step (Art. 33(3) PCT)**

3.1 Claims 6 and 7 differ from D1 or D2 (considered to represent the closest prior art documents for present claims 6 and 7) in that the compositions of claims 6 and 7 comprise Tea Tree oil as antimicrobial agent. The **problem** of present claims 6 and 7 can therefore be formulated as which other antimicrobial agent could be used instead of those already mentioned in D1 or D2. The **solution** given in claims 6 and 7 is to use Tea Tree oil. Although the antimicrobial properties of the Tea Tree oil were already known (see for example D4), none of the documents mentioned in the international search report point to compositions comprising Tea Tree oil in a film forming liquid. D4 suggest the use of Tea Tree oil in semisolid formulations (creams and gels) for the treatment of burns, tinea and acne. Therefore, the subject-matter of present claims 6 and 7 is considered to involve an inventive step.

3.2 There is no hint in the prior art for the use of a water resistant and antimicrobial film for the preparation of a medicament for the topical treatment of water related outer ear canal disorders.

3.3 Therefore, claims 1, 6 and 7 seem to be inventive in the light of the documents cited in the international search report taken alone or in combination.

**4. Industrial applicability (Art. 33(4) PCT)**

4.1 For the assessment of the present claim 1 on the question whether it is industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

4.2 Present claims 2-7 are susceptible of industrial application and thus do not contravene Art. 33(4) PCT.